**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

(Attorney Docket No. 006401.00418)

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| In re application of: | ) | |
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| Lin Wang | ) | Group Art Unit: 1732 |
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| Serial No: 10/687,498 | ) | Examiner: Monica A. Huson |
| | ) | |
| Filed: March 25, 2004 | ) | Confirmation No.: 9050 |
| | ) | |
| For: Process Using Cold-Water Soluble Extruded Starch | ) | |

**REPLY BRIEF**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The Examiner's Answer is replete with inaccurate statements about the prior art and is riddled with legal errors. Examiner Huson seems to have ignored all of the factual and legal requirements necessary for maintenance of a Section 103 rejection. The various errors in the Examiner's logic are discussed below.

**Nakatsuka does not disclose forming a film from a solution.**

The invention of claim 1 specifies providing a *solution* of an extruded starch product and "forming a film from said solution." Nakatsuka simply does not teach these claimed steps, as applicant pointed out in the initial Appeal Brief. In response, the

Examiner indicates that this is "not persuasive because Nakatsuka clearly describes forming a film at column 4, lines 5-10."

The Examiner is wrong. Nakatsuka does state, at column 4, that his molding composition can be used in various applications including "sheet, film, tubing, and bottle or other containers." But the claimed invention specifies *forming a film from a solution,* which Nakatsuka does not teach at all. Nakatsuka forms the various structures disclosed by feeding his starch/protein composition to an extruder or injection molding machine.

In fact, Nakatsuka teaches directly away from forming a film from a solution. At column 1, line 65, Nakatsuka discusses the "so-called film casting method" in which film is formed from a solution. He characterizes this method as having "its own fatal disadvantages."

How could Nakatsuka possibly render obvious the claimed invention? The invention specifies forming a film from a solution. Nakatsuka does not teach this. Nakatsuka instead characterizes the "film coating method" as a process with "fatal disadvantages." On this basis alone, the rejection must be reversed.

**Nakatsuka does not teach an extruded starch product**

The Examiner clings to the assertion that Nakatsuka discloses an extruded starch product, when the teachings of Nakatsuka are directly to the contrary. Again, as discussed at column 6, Nakatsuka teaches that "some degree of union has been established between both materials [starch and protein] by chemical reaction." At column 6, line 48, Nakatsuka further teaches that the occurrence of chemical reaction is demonstrated by the facts that "the dissolution speed of the mixture in cold water decreases," a "pale yellow discoloration of the mixture appears," and "a characteristic

odor is emitted." A material composed only of starch would not be described as exhibiting "discoloration," or as having a "characteristic odor."

What is the Examiner's response? While conceding that "Nakatsuka does not specifically identify the exact composition of the final article," the Examiner states that an "'extruded starch product' is easily defined as a product made of extruded starch." In other words, says the Examiner, because starch goes into an extruder, the product that comes out of the extruder is of necessity an "extruded starch product" irrespective of what happens in the extruder and irrespective of Nakatsuka's direct teachings to the contrary. The Examiner is incorrect. A "starch product" connotes carbohydrate structure, which Nakatsuka suggests is absent. By the Examiner's logic, water would be a "hydrocarbon product," because water is produced in an engine upon combustion of hydrocarbons.

The Examiner also argues that Nakatsuka's claim 20 discloses a "starch." In fact, claim 20 specifies a film made from protein and starch. Claim 20 must be read as part of Nakatsuka's specification, not as an independent disclosure. Specifically, claim 20 cannot be read as an independent teaching that the product of Nakatsuka is a starch.

**The claimed gelatinization is not taught by Nakatsuka**

The claimed invention specifies that the extruder barrel has at least two zones where the temperature in the first zone is insufficient to gelatinize the starch to a gelatinization level of at least 95%, but the temperature in the second zone is sufficient to so gelatinize the starch. Where are these teachings in Nakatsuka? The Examiner contends that "gelatinization occurs at about 150° to 175° C," so that of necessity Nakatsuka meets the claims.

As an initial matter, the Examiner's general assertion as to the gelatinization temperature of starch is unsupported. She does not indicate, for instance, how the effects of pressure or the type of starch would affect the gelatinization temperature.

More fundamentally, however, the product of Nakatsuka is not a starch but is a product in which "some degree of union has been established." How could the Examiner possibly know what the gelatinization temperature of this product would be? "Gelatinization" is a phenomenon of starch, and it is unclear whether the product of Nakatsuka, with its "discoloration" and "characteristic odor" is even susceptible of gelatinization.

Even if one were somehow to overlook the foregoing, the Examiner still would be wrong. To the extent that Nakatsuka could suggest somehow that gelatinization occurs, how would the Examiner know what the extent of gelatinization would be? The Examiner is arguing that the claimed steps are inherent in Nakatsuka, but this argument runs afoul of law. *See* M.P.E.P. 2112 and cases cited therein, in particular *Ex parte Levy*, 17 USPQ2d 1461 (Bd. Pat. App. & Inter. 1990). In *Levy*, overturning the Examiner, the court held that in "relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Id.* at 1464. Similarly, in *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981), the C.C.P.A. overturned an Examiner on similar grounds, holding that "[i]nherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient."

Here, there is no way the Examiner could know whether "the temperature in [the] first zone" of Nakatsuka's equipment is "insufficient to gelatinize said starch to a

gelatinization level of at least 95%." The Examiner likewise has provided no basis for demonstrating that "the temperature in said second zone" is "sufficient to gelatinize said starch to a gelatinization level of at least 95%." The rejection must be overturned for this independent reason.

**The Altieri reference adds nothing to overcome the defects in Nakatsuka**

The Examiner relies on Altieri solely for purposes of barrel moisture content. Altieri does not overcome Nakatsuka's omissions and contrary teachings, and does not support the rejection of claims 1-6.

**Redding Jr. is incompatible with Nakatsuka and Altieri**

As discussed in Applicant's opening brief, the references cited to reject claim 7 are incompatible with one another and with the invention of claim 7. First, Redding, Jr. reference teaches away from modifying starch, while Nakatsuka teaches exactly the opposite. Redding, Jr. and Nakatsuka are hence incompatible. Second, the claimed invention specifies hydroxyalkyl starches. Redding, Jr. teaches away from modified starches and hence from this aspect of the claimed invention. Third, the Altieri reference teaches directly away from the particle size distribution specified in claims. Altieri is inconsistent with claim 7 and incompatible with Redding, Jr.

The Examiner's response to this argument is factually inaccurate and legally wrong. First, she points to column 2 of Nakatsuka and asserts that '[i]n fact, Nakatsuka, like Redding, also teaches that chemical modification of starch is undesirable." That assertion is preposterous and reflects the Examiner's tortured misreading of the reference. The portion of Nakatsuka cited by the Examiner discusses certain unidentified prior art

processes that have the effect of "spoiling the edibility" of the starch. Nakatsuka's answer to these prior art processes is to modify the starch with protein in a manner that does not spoil the edibility. Far from teaching that chemical modification of starch is undesirable, Nakatsuka teaches that "chemical reaction between [starch and protein] . . . ***is desirable*** for the improvement of the molded articles in appearance, particularly transparency and in physical properties . . . ." Col. 6 ll. 41-47 (emphasis added). Indeed, the whole point of Nakatsuka is to modify the starch with the protein. Contrast this with Redding, Jr.'s desire "to provide a cost effective and energy efficient method of physical modification of starch and other substrates *without the necessity of chemical additives*," Column 3, lines 46-49 (emphasis added). Nakatsuka may characterize one specific prior art process as being undesirable, but that does not mean that Nakatsuka teaches generally that starch modification is undesirable.

Second, the Examiner asserts that it is acceptable to ignore the fundamental incompatibility of the cited references. As discussed in appellant's opening brief, this is legal error. What is the Examiner's response? In her Answer, the Examiner has failed to respond to the argument that Altieri is an incompatible reference. She likewise has ignored the fact that Redding, Jr. is incompatible, stating that this reference "was not cited to show hydroxyalkyl starch components." In other words, the Examiner feels free to reach into the prior art to cobble together the elements of the claimed invention. The fact that the references are incompatible with each other is of no moment to the Examiner.

Recently, the Board decided *Ex parte Whalen II*, Appeal 2007-4423 (July 23, 2008). This decision confirmed the holding in *KSR Int'l Co. v. Teleflex Inc.*, 125. Ct. 1727, 1741 (2007) that an invention "composed of several elements is not proved obvious merely by demonstrating that each of its elements was known in the prior art." The *Whalen II*

decision contains language especially applicable here. When the prior art "teaches away from the claimed [invention]," obviousness is particularly difficult to demonstrate. The Board held that "it must be shown that those of ordinary skill in the art would have had some reason to modify the known [prior art] in a way that it would result in the claimed [invention]."

Here, the Examiner's attempt to combine Nakatsuka and Redding Jr. is exactly what is proscribed by the *KSR* case and by the *Whalen II* decision. The Examiner has reached into the Altieri and Redding, Jr. reference to find various elements of the claimed invention, in an attempt to "demonstrat[e] that each of its elements was known in the prior art." She has ignored everything else in Redding, Jr. and in Altieri. She has failed to show why someone skilled in the art possibly would overlook the fundamental incompatibility of Redding, Jr. and Nakatsuka. Nakatsuka teaches to modify starch very substantially, while Redding, Jr. cautions against modifying starch. Why would one of skill in the art have thought to combine these teachings, despite the incompatibility of these references? The Examiner does not say. Likewise, Altieri teaches directly away from the claimed particle size and is incompatible with claim 7, and likewise is not compatible with Redding, Jr. Why would it have been obvious to have overlooked this incompatibility?

The Examiner has not even attempted to meet the requirements of *KSR* and *Whalen, II* to this effect. Instead, the Examiner *acknowledges* that she is picking and choosing details from the Redding, Jr. and Altieri references while ignoring incompatibility of these references. She bases her rejection solely on the fact that certain elements of the invention are found in the art. This is exactly what *Whalen II* says the Examiner should not do.

**Summary**

Thus, the Examiner's analysis is fundamentally flawed on many levels. She starts with the Nakatsuka reference, a reference that not only fails to teach the claimed process of forming a film from solution, but also that teaches that this type of process "has its own fatal disadvantages." From this inauspicious start, she incorrectly reads Nakatsuka to teach an extruded starch product, when in fact Nakatsuka's teachings are directly to the contrary. Moreover, although it is not known whether the material of Nakatsuka is capable of gelatinization, or what the gelatinization temperature of this material would be in Nakatsuka's equipment, the Examiner concludes that these elements of the claimed invention are met. To arrive at this conclusion, she first plucks a gelatinization value out of the air, and states that the material of Nakatsuka gelatinizes at this temperature. She then concludes that elements requiring plural zones are found in Nakatsuka.

When rejecting claim 7, the Examiner continues the above errors and continues with an incorrect reading of Nakatsuka. From here, the Examiner ignores the requirements of law, including the recent *Whalen II* decision, by selecting bits and pieces from the Altieri and Redding, Jr. references while ignoring the rest of these references. She has ignored completely the fundamental incapability of these references with each other and with the claimed invention.

The Examiner's reasoning is fundamentally improper, and the claim rejections must be reversed.

Respectfully submitted,

Dated: 5/16/08

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